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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/802,427

03/17/2004

Gustavo C. Rodriguez

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03/10/2008

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

03/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/802,427	<b>Applicant(s)</b> RODRIGUEZ, GUSTAVO C.	
	<b>Examiner</b> Raymond J. Henley III	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/2/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

**CLAIMS 1 AND 3-26 ARE PRESENTED FOR EXAMINATION**

Applicant's Information Disclosure Statement filed August 2, 2006 and amendment filed May 11, 2007 have been received and entered into the application. Accordingly, the specification at page 1 and claims 1 and 9 have been amended and claim 2 has been canceled. Also, as reflected by the attached, completed copies of form PTO/SB/08/a&b, (8 sheets), the cited references have been considered.

In light of Applicant's amendment, (i) the objection to the specification and rejection of claims 1, 8 and 12 under 35 U.S.C. 102(b) as being anticipated by Carlstrom et al., as set forth in the previous Office action dated July 28, 2006 has been overcome and thus is here withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejection - 35 USC § 103***

Claims 1, 3-5 and 8-26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen, (U.S. Patent No. 4,855,305, newly cited by the Examiner) in view of Gast, (U.S. Patent No. 5,747,480, already of record), each of record, for the reasons of record as set forth in the previous Office action dated July 28, 2006 at pages 3-7 as applied to claims 1-5 and 8-26, which reasons are here incorporated by reference.

Applicant's remarks at page 5 of the amendment have been given careful consideration, but fail to persuade the Examiner of error in his determination of obviousness.

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Applicant has traversed the present rejection on the grounds that “Cohen teaches a broad range of dosages and does not teach the numerical combinations recited in Applicants' claims”.

However, it is well established that “Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)” (see MPEP 2144.05(II)). The determination of the optimum dosage regimen to employ with the presently claimed active agents would have been a matter well within the purview of one of ordinary skill in the art and such determination would have been made in accordance with a variety of factors. These would have included the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered a part of a drug combination. Thus, the dosage regimen that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage amounts are not seen to be inconsistent with the dosages that would have been determined by the skilled artisan.

Here, the reference provides for a range of dosage amounts that encompasses the presently claimed dosage amounts. Applicant has not established that the presently claimed dosage amounts provides for any therapeutic result that would not have been expected by one of ordinary skill in the art.

Accordingly, the Examiner will maintain his position that the presently claimed subject matter would have been obvious.

***Double Patenting***

Claims 1 and 3-26 and rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,511,970, for the reasons of record as set forth in the previous Office action dated July 28, 2006, as applied to claims 1-26, which reasons are here incorporated by reference.

Applicant's remarks at page 5 of their response have been given careful consideration, but fail to persuade the Examiner of error.

In particular, Applicant has traversed the present rejection on the grounds that norgestrel and levonorgestrel are distinct products. The basis of the Examiner's rejection, however, does not stand on the proposition that these two compounds are equivalent. Rather, it is the Examiner's position that levonorgestrel and norgestrel are enantiomers of each other and thus would have been present in the patented hormonal regimen.

Applicant's remarks do not refute this proposition. Accordingly, the rejection will stand as proper.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

None of the claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

February 17, 2008

/Raymond J Henley III/  
Primary Examiner, Art Unit 1614